

REMARKS

Prior to discussing the rejections in the Final Action of May 16, 2007, and the above amendments to the claims, applicants hereby request a personal interview be granted to their undersigned representative prior to the first Action in the RCE of which this submission is a part. The undersigned representative respectfully requests that the Examiner contact him at 202-887-9023 to schedule an interview.

Referring to the Final Action, claims 2-6 and 10-14 are again rejected under 35 U.S.C. 102(b) as being anticipated by, and claims 7-9 are again rejected under 35 U.S.C. 103(a) as being unpatentable over, Elias et al. (U.S. Patent No. 5,549,566) ("Elias").

The Office's statement of rejection on pages 2 to 7 of the Final Action is essentially identical to that of the first Action of October 5, 2006. The only difference appears to be the assertion that the limitations directed to compression of the seal in the claims of the present application are being interpreted as intended use limitations which would be met by a structure capable of performing the intended use (see the paragraph bridging pages 3 and 4 of the action).

Applicants submit initially that the rejections of the claims of the present application (in their form prior to the amendments

made herein) are based on an unreasonably broad interpretation of the claims and, particularly, the limitations "solid spike" and "solid structure". Examiners are permitted to give claims their broadest reasonable interpretation. However, such interpretation must be consistent with the specification. Moreover, claim language is to be "read in light of the specification as it would be interpreted by one of ordinary skill in the art." See *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990) quoted with approval in *In re American Academy of Science Tech Center*, 70 USPQ2D 1827 (Fed. Cir. 2004).

In the present case, in response to the argument made by applicants in the response filed February 5, 2007, to the first Action that the spike of the present invention has a solid structure, the Office has noted "[t]he Examiner maintains the spike [of Elias] is solid as broadly claimed, as compared to a liquid structure." I.e., the position of the Office is that the claims can be broadly interpreted as reading on a spike that IS MADE OF A SOLID AS OPPOSED TO BEING MADE OF A LIQUID. This is not a reasonable interpretation.

First, the interpretation is not consistent with the specification. The term "solid" is used in the claims as an adjective. It is clear from the specification that the term is

intended to have its ordinary meaning "being without an internal cavity". (See the attached printout from the 2003 edition of Merriam-Webster's Unabridged Dictionary). The specification of the present application distinguishes the medical valve and spike of the present invention over a medical valve disclosed in U.S. Patent No. 6,029,946 in which a fluid transferring passage is formed in the "inside of the spike." (See, *inter alia*, page 2, line 12, of the specification).

Second, a person of ordinary skill in the art would not interpreted the terminology "solid spike" or "solid structure" as being anything other than a "liquid structure" because the term "solid", when used to distinguish over a gas or liquid, is used as a noun (i.e., "a solid") - not as an adjective. Additionally, a person of ordinary skill in the art would recognize that the term is used in the specification of the present application according to its ordinary meaning as explained above. A person of ordinary skill in the art would also understand that the terminology "solid structure" has a meaning other than simply a non-solid, i.e., other than not being a liquid, because medical valves having a liquid structure are not known in the art. The Office has not identified any medical valves in the prior art having a liquid structure.

Referring to interpretations given by the Office to other claims, claim 2 was amended in the response to the first Action to recite that the transferring passage extends "through the entire longitudinal length in the peripheral surface of the spike". The Office has taken the position in the Final Action that claim 2 does not specify through which longitudinal length the passage extends and asserts that the claim can be interpreted, for example, as meaning "the entire longitudinal length of the intermediate portion of the valve". This interpretation is not reasonable because nothing in the specification or claims identifies an intermediate portion of the valve or spike which the limitation could modify.

Regarding claim 3, the Office has taken the position that Fig. 3 of Elias shows branch portions 18a formed on element 18. Claim 3, however, in the form examined by the Office in the Final Action, recites that the branch portions are formed integrally with and branch off from a joining portion that constitutes the top end portion of the spike. The portions 18a of the device of Elias are "ribs" extending radially around the cannula of the device and are not formed integrally with head portion 50a (identified by the Office as equivalent to the joining portion).

Notwithstanding these and other interpretations that are not consistent with the specification and would not be given to the

terminology by a person of ordinary skill in the art when the claims are read in light of the specification, the claims have been amended to recite the medical valve of the invention in terms that are consistent with and supported by the description of the valve in the specification and drawings and consistent with the recitation of the valve in the original claims. As amended, the claims avoid the interpretations given by the Office to the original claims and clearly distinguish over the infusion device of Elias.

Referring to the amendments, claim 2 has been amended to recite the spike of the medical valve as being a longitudinal solid spike disposed to extend longitudinally in the housing and as having a groove-shaped fluid transferring passage which extends the entire longitudinal length of the spike and is formed on the outer peripheral surface of the spike.

Claim 3 has been amended to recite the spike of the medical valve as being a longitudinal spike which comprises a joining portion constituting the top end portion of the spike, and a plurality of longitudinal branch portions formed integrally with the joining portion and branching off from the joining portion, each longitudinal branch portion extending downwardly from the joining portion to the fluid circuit. Claim 3 has been further

amended to recite that the fluid transferring passage is defined between the branch portions and an inner surface of the elastic seal.

Claim 4 has been amended to recite the spike of the medical valve as being a longitudinal spike which comprises a plurality of longitudinal divided bodies which are formed into one pair in axial symmetry and extend longitudinally along the entire length of the spike. Claim 4 has also been amended to recite that the fluid transferring passage is defined between the divided portions and an inner surface of the elastic seal.

Claim 5 has been amended to recite the spike of the medical valve as being a longitudinal spike which comprises two main longitudinal portions extending along the entire longitudinal length of the spike and a bridge portion formed integrally with the main portions and disposed between a segment of the main portions to join the main portions together and to recite that the fluid transferring passage is defined between the main portions and an inner surface of the elastic seal.

Claim 6 has been amended to recite the spike of the medical valve as being a longitudinal spike wherein a fluid transferring passage extends longitudinally in the outer peripheral surface of

the spike and is formed between the outer peripheral surface of the spike and an inner surface of the elastic seal.

Claim 7, which depends on claim 2, has been amended to define the spike as comprising at least three longitudinally extending fins projecting radially outwardly from the axial portion, with fluid transferring passages being defined between adjacent ones of the fins and an inner surface of the elastic seal.

In light of these amendments to the claims and in light of the above comments concerning the proper interpretation to be given to claim terminology, applicants respectfully submit that Elias is insufficient to support a rejection of the claims for anticipation under 35 U.S.C. 102(b) and is insufficient to support a case of prima facie obviousness of the claims under 35 U.S.C. 103(a). Removal of the rejections of the claims is believed to be in order and is respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated May 16, 2007.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time.

RECEIVED
CENTRAL FAX CENTER

OCT 16 2007

PATENT APPLN. NO. 10/800,913
SUBMISSION UNDER 37 C.F.R. § 1.114

PATENT

The fee for any such extension and any additional required fees may be charged to our Deposit Account No. 111833.

Respectfully submitted,
KUBOVCIK & KUBOVCIK



Ronald J. Kubovcik
Reg. No. 25,401

Suite 710
900 17th Street, N.W.
Washington, D.C. 20006
Tel: (202) 887-9023
Fax: (202) 887-9093
RJK/JBF

Attachment: Printout of the meaning of "solid" (adj.) from the 2003 edition of Merriam-Webster's Unabridged Dictionary

Main Entry: **isol·id**
Pronunciation: 'säləd
Function: *adjective*
Inflected Form: -er/-est
Etymology: Middle English *solide*, from Middle French, from Latin *solidus*; akin to Greek *holos*, entire — more at **SAFE**

- 1 a : having an interior filled with matter : being without an internal cavity *(the knob is heavy because it is solid)* *(the stalks of some plants are not solid)* *(a solid tire)* — opposed to *hollow* b (1) : set in type without leads or other spacing material between the lines : **CLOSE** *(a forbidding page full of solid black paragraphs)* (2) : having no intervening space *(the solid elements of a compound word)* c : not interrupted by any break or opening *(the outer walls solid and windowless)* *(the law requires a driver to stay on his own side of the solid line)*
- 2 a : having or involving three dimensions : **CUBIC** *(a solid paraboloid)* *(a solid foot contains 1728 solid inches)* b : of, relating to, or dealing with solid magnitudes *(a solid equation)* — see **SOLID GEOMETRY**
- 3 a : marked by density or compactness : of uniformly close and coherent texture or consistency : not disintegrated, loose, or spongy *(a solid mass of rock)* *(rain fell in solid sheets)* *(the surgeon scraped back to solid healthy bone)* b : possessing or characterized by the properties of a solid : being neither gaseous nor liquid *(the pavement is not yet solid)* *(physics of the solid state)*
- 4 : of good and substantial quality or kind *(solid comfort)*: as a : having merit or soundness *(based his decision on solid reasons)* b : made firmly and well : **STURDY** *(a solid chair)* *(firm solid walls)* c (1) : full sounding and having a strong rhythmic drive *(solid jazz music)* (2) : excellent in every respect — used especially of popular music d *of immunity* : capable of resisting severe challenge *(intradermal inoculation of the virulent agent in guinea pigs resulted in solid immunity in all trials)*
- 5 : united or consolidated so as to form an integral whole: as a *of time* : having no break or interruption *(stand for three solid hours)* b : **UNANIMOUS** *(a solid delegation)* *(the solid vote of a delegation)* *(group opinion is solid)* c : united or joined in intimacy : being on good terms — used with *with* *(make oneself solid with the chief)*
- 6 a : having or marked by sound judgment or knowledge : thoroughly grounded *(solid thinkers)* *(solid learning)* b : **SERIOUS-MINDED, RELIABLE, PRUDENT; often** : well-established financially : having unimpaired credit *(solid New Englanders)* *(the solid men of the community)* c : serious in purpose or character : not trivial : not vain or frivolous *(time for solid reading)*
- 7 : entirely of one substance, formation, kind, or character: as a : entirely of one metal : containing the minimum of alloy necessary to impart hardness *(solid gold)* b : being or consisting of a single uniform color or tone c : having decorative details worked on solid material *(a solid frame)*
- synonyms see **FIRM**